

## **REMARKS**

Claims 1-17, 20, 21, 23, 26 and 27 are pending in the application, of which Claims 1, 4-6, 17-19, 21-25 and 27 have been withdrawn. By way of this amendment Claims 4-6, 17, 21 and 23 have been cancelled. The Applicants reserve the right to further prosecute the subject matter of the withdrawn and cancelled Claims in a divisional, continuation, continuation-in-part application at a later time. Claim 27 has been amended to depend from Claim 1. No new matter has been added.

In the Office Action Claims 17, 21 and 23 have been objected to for being substantial duplicates of Claims 1 and 5. By way of this amendment, Claims 17, 21 and 23 have been cancelled and therefore this objection is now moot.

In the Office Action, Claims 17, 21, 23 and 27 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. By way of this amendment, Claims 17, 21 and 23 have been cancelled and the dependency of claim 27 changed to Claim 1. In view of the foregoing, the rejection of Claims 17, 21, and 23 are now moot. Claim 23 now depends from Claim 1 and it is respectfully requested that the rejection of Claim 23 be reconsidered and withdrawn.

In the Office Action, Claims 1, 4, 5, 17, 21, 23 and 27 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner has alleged that these claims are directed to

methods of converting a fatty acid to its corresponding dicarboxylic acid using a genus of NCP or NCP1B genes involved in carboxylic acid production. The Examiner has acknowledged that the instant specification teaches the structure and function of the *C. tropicalis* NCP1B gene. By way of this amendment, Claim 1 has been amended to the *C. tropicalis* NCP1B gene. In view of the foregoing amendments and cancellation of claims, the rejection of Claims 4,5,17,21 and 23 under 35 U.S.C. §112, first paragraph is now moot. In view of the foregoing amendments and remarks, it is respectfully requested that the rejection of Claims 1 and 27 be reconsidered and withdrawn.

Similarly, Claims 1,4,5,17, 21, 23 and 27 have been rejected under 35 U.S.C. §112, second paragraph as allegedly not being enabled by the specification. The Examiner has acknowledged that the specification does enable methods of converting a fatty acid to its corresponding dicarboxylic acid using *C. tropicalis* POX4 promoter fused to the *C. tropicalis* NCP1B gene. In view of the fact that Claim 1 has been amended to the *C. tropicalis* NCP1B gene it is respectfully asserted that Claims 1 and 27 are fully enabled by the specification and that the rejection of Claims 1 and 27 be reconsidered and withdrawn. Claims 4, 5, 17, 21, and 23 have been cancelled and therefore the rejection as it pertains to these Claims are now moot.

Turning to the rejections of the Claims on the merits.

In the Office Action, Claims 1, 4-6, 17, 21, 23 and 27 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over either Wilson et al.(US Patent 6,331,420) or Wilson et al . (WO 00/20566- herein WO '566). Since Claims 4-6, 17, 21 and 23 have been cancelled , this rejection as it pertains to these claims is moot.

As acknowledged by the Examiner at page 11, last full paragraph of the Office Action, Wilson does "not teach *Candida tropicalis* POX4 promoter." However, the Examiner contends that Wilson et al. teaches the methods of converting a fatty acid to its corresponding dicarboxylic acid comprising transforming a suitable host cell with a *C. tropicalis* CPR B gene, (which the Examiner further contends that is identical to the *C. tropicalis* NCP1B gene of the instant application) and culturing the cell in the presence of an organic substance that is biooxidizable to fatty acids. (See Office Action pages 6-7). The Examiner then stated that Wilson teaches that the existing promoter of the CPR genes can be replaced with a strong promoter and provides the *Candida* POX4 promoter as a strong promoter and yeast as a potential suitable host cell line. (See Office Action page 7).

The Examiner then relied on Okazaki et. al., a publication that was available at the time the Wilson applications were filed, as teaching the *Candida tropicalis* POX4 promoter and for teaching that the POX4 gene are induced by growth on fatty acids or

alkanes. With this, the Examiner contends that it would have been obvious to one skilled in the art to use *Candida tropicalis* POX4 promoter of Okazaki et al. in the methods of Wilson et al (US '420) or (WO 00/20566).

Applicants respectfully disagree and traverse the rejection for the following reasons.

In order to establish a *prima facie* case of obviousness it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, that one having ordinary skill in the art would have been led to do what the applicants have done. See *Ex parte Levengood*, 28 USPQ2d 1300, 1301 (BPAI 1993); and *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353-54 (Bd. App.1984). In short, the citations must "suggest the desirability of the combination" that is claimed. MPEP 2143.01 at 2100-110, 111 and MPEP 2145 (j) 3 at 2100-127. Statements with regard to relevant skill in the art do not suffice to "bridge over gaps in substantive presentation of an obviousness case." *Al-site Corp. v. VSI International, Inc.*, 174 50 USPQ2d 1161 (Fed. Cir. 1999). The Applicants respectfully submit that the cited reference fails to provide the requisite suggestion to do what the Applicants have done. That is, simply stating that POX 4 is a promoter in a single reference does not provide a disclosure which would have "*strongly motivated*" one skilled in the art to deviate from using the promoter disclosed in the prior art reference and replacing it with the claimed promoter. It does not provide the motivation which would have "*impelled*" one skilled in the art to do so. *Ex parte Graselli*, 23 USPQ 393, 394 (Bd. App. 1986). But that is what a conclusion of obviousness requires. See *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). For these reasons

alone, the rejection of the Claims is insufficient as a matter of law. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993).

Moreover, the Okazaki et al reference published in October 1985 and therefore was available to the inventors of both US '420 and WO '566 to Wilson et al. at the time these patent applications were filed. However, with this reference in hand, even the inventors of US '420 and WO '566 to Wilson et al. failed to see what the Examiner claims is obvious and did not teach or suggest the claimed invention in either of these references. Surely, if the claimed invention is so obvious over the cited references then the later filed references to Wilson having the earlier published reference to Okazaki in hand would have at least mentioned the claimed invention in their patent application. But that is not the fact. Therefore, this is but yet further evidence that these references fail to provide the required suggestion and/or motivation to do what the Applicants have done.

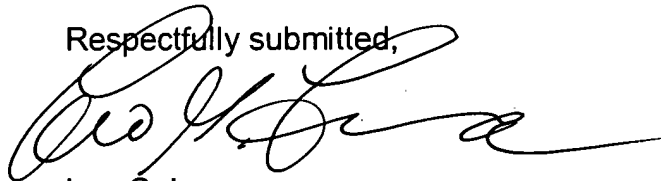
In fact, what the rejection distills down to is that one "*could have*" or "*would have been able to*" do what the Applicants have done. That, however, is not the standard under 35 U.S.C. § 103(a), and has long been rejected as a substitute for the elements required of an Examiner to meet the burden of establishing a *prima facie* case of obviousness. See MPEP 2143.01 at 2100-2111; and see *Ex parte Levengood*, supra at 1301; and see *Ex parte Markowitz*, 143 USPQ 303, 305 (Bd. App. 1964).

After considering the information stated above, it also becomes apparent then, based on the rejection, the references, and the Examiner's reasoning, that the obviousness rejection made by the Examiner was based on *impermissible hindsight recreation* of the claims based upon a blue print of the invention provided by the teachings of the application. However, it is fundamental that it is impermissible within the framework of §103 to use the Applicants' application as a blue print for choosing

particular elements from references to the exclusion of other elements taught by the reference so as to arrive at the claimed invention. *In re Wesslau*, 147 USPQ 391,393 (CCPA 1965). Therefore, for all of the foregoing reasons, it is respectfully submitted that the Examiner has not met his burden of establishing a *prima facie* case of obviousness of the claims under either of the Wilson et al. references in view of Okazaki et al. In view of the foregoing amendments and remarks, Applicants respectfully assert the Claims are now in condition for allowance and allowance of all Claims is respectfully requested.

Early favorable action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Leo G. Lenna', written over the typed name.

Leo G. Lenna  
Reg. No. 42,796  
Attorney for Applicants

DILWORTH & BARRESE  
333 Earle Ovington Blvd.  
Uniondale, NY 11553  
Tel. (516) 228-8484  
FAX (516) 228-8516